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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,473	11/08/2001	Michael Hagen	33,482-00	3152
25291	7590	07/14/2006	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,473	HAGEN, MICHAEL	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/23/06, 03/13/06 and 04/06/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 88-90, 98, 105, 109, 116-119, 160, 163-164, 167 and 186-199 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/23/06, 03/13/06 and 04/06/06 have been entered.

Status of claims

2. Claims 1-87, 91-97, 120-126, 131-137, 142-148, 153-159, 161, 165, 169, 172, 175, 178, 181 and 184 are cancelled. Claims 186-199 are added. Claims 88-90, 98-119, 127-130, 138-141, 149-152, 160, 162-164, 166-168, 170-171, 173-174, 176-177, 179-180, 182-183, and 185-199 are pending. Claims 99-104, 106-108, 110-115, 127-130, 138-141, 149-152, 162, 166, 168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2004 and 01/28/05.

Claims 88-90, 98, 105, 109, 116-119, 160, 163-164, 167 and 186-199 are under examination.

Election/Restrictions

3. The following lack of unity requirement is necessitated by Applicant's amendment to the claims. Newly submitted claims are directed to an invention that is independent or distinct or lack unity from the invention originally claimed for the following reasons: The originally filed and examined claims are directed to a composition consisting of an antigen and an adjuvant, wherein the adjuvant is the combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and a cytokine. The instantly pending claims are directed to two different inventions that lack unity with one another. The first invention, Group I, claim(s) 88-90, 98, 105, 109, 116-119, 160, 163-164 and 167, drawn to a composition consisting of an antigen and an adjuvant, wherein the adjuvant is the combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and a granulocyte macrophage colony stimulating factor (GM-CSF), and method of using the composition. The second invention, Group II, claim(s) 186-199, drawn to a composition consisting of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and a interleukin 12 (IL-12), and method of using the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the claims are subjected to a restriction.

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 88-90, 98, 105, 109, 116-119, 160, 163-164 and 167, drawn to a composition consisting of an antigen and an adjuvant, wherein the adjuvant is the combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and a granulocyte macrophage colony stimulating factor (GM-CSF), and method of using the composition.

Group II, claim(s) 186-199, drawn to a composition consisting of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and an interleukin 12 (IL-12), and method of using the composition.

5. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant, the inventions lack the same or corresponding special technical feature. The special technical feature of Group I is the combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and a granulocyte macrophage colony stimulating factor (GM-CSF). The special technical feature of Group II is the combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and an interleukin 12 (IL-12). These cited special technical features differ from one another. Hence, the inventions lack the same or corresponding special technical feature.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.


Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Emily Le 7/07/06
Patent Examiner
Art Unit 1648

Continuation of Disposition of Claims: Claims pending in the application are 88-90,98-119,127-130,138-141,149-152,160,162-164,166-168,170,171,173,174,176,177,179,180,182,183 and 185-199.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 99-104,106-108,110-115,127-130,138-141,149-152,162,166,168,170,171,173,174,176,177,179,180,182,183 and 185.